

REMARKS

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. Any amendment should not be construed as an admission regarding the propriety of any objection or rejection raised in any Office Action, and the Applicant reserves the right to pursue the full scope of the unamended claims in any subsequent patent application as may be appropriate. It is believed the amendments fully respond to the issues raised in the Office Action. Further detail with respect to specific points raised in the Office Action is offered below.

Included with the Applicant's current response is an Information Disclosure Statement. Although the Information Disclosure Statement provides additional information for the Office to consider, such information possibly may be material to patentability and accordingly the Information Disclosure Statement is believed by the Applicant to be the only means to comply with its duties under 37 C.F.R. § 1.56. Additionally, the Information Disclosure Statement is believed to address at least in part the concerns raised by the Office in the Office Action dated March 14, 2006 with respect to Applicant's previous Information Disclosure Statement submitted December 13, 2005.

As a preliminary matter, the Applicant notes that many of the issues and concerns related to the present case may present complex and intertwining considerations. Accordingly, in the event questions remain, the Applicant requests the opportunity to pursue an interview to resolve any issues or concerns.

The Office raises certain new matter concerns with respect to the claims. With regard to these new matter concerns, the Applicant believes that the disclosure in the specification at pages

22-23 obviates the same. In particular, the Applicant believes the recovery of embryos from 9 of 12 heifers, as discussed at pages 22-23, is clear evidence of at least a 75% fertilization success rate. Moreover, by way of comparing this 75% fertilization success rate to a “typical unsorted insemination dosage”, as is recited in claim 124 (d), the Applicant points to the Seidel (1997) publication cited at page 19, lines 16-18 of the specification and incorporated by reference. There, insemination with a typical dosage of sperm (2.5×10^6) yielded pregnancy rates of 62% for ipsi-lateral insemination and 50% for contra-lateral insemination. The Applicant notes the Office, in the Office Action at page 3, has considered this dosage of sperm (2.5×10^6) to be “typical”, and therefore the Applicant treats it as the same. Pointedly, comparison of the 75% fertilization success rate demonstrated in the example at pages 22-23 of the specification with the 62% pregnancy rate and the 50% pregnancy rate demonstrated in the citation to the Seidel (1997) publication at page 19 of the specification illustrates that claim 124 (d) is enabled for the recitation of “at least 35%, at least 41%, at least 50%, and at least 90% of a typical unsorted insemination dosage”. Specifically, the 75% fertilization success rate is equal to 121% of the 62% pregnancy rate ($0.75 / 0.62 = 1.21$), and the 75% fertilization success rate is equal to 150% of the 50% pregnancy rate ($0.75 / 0.5 = 1.50$). Accordingly, it is believed the claims present no new matter in light of the disclosure at pages 22-23 of the specification.

The Office raises a number of enablement concerns. For the reasons discussed above with respect to the example on pages 22-23 of the specification, the Applicant believes the claims are enabled with respect to a method in which fertilization success rates of at least 35%, at least 41%, at least 50%, and at least 90% of a typical unsorted insemination dosage are achieved.

Moreover, the Applicant disagrees that the dosage utilized in the example at pages 22-23 of the specification is not about one-half the number of sperm cells of a typical unsorted insemination dosage. However, please note the applicant has amended claim 124 to add the recitation of “but at least about 619,000 sperm cells”. This amendment is made solely to facilitate examination of the case, and should not be construed as an admission or estoppel by the Applicant. Nevertheless, the amendment is believed to address the enablement concerns raised by the Office on this point.

In addition, the Applicant disagrees that the various factors set forth in the Office Action are critical parameters. These factors are discussed in the specification with respect to a variety of embodiments, including embodiments unrelated to the superovulation aspects that are the subject of the current claims, and are not described by the specification as being critical to the superovulation aspects at hand. For example, the Office Action lists several factors – such as the time at which sperm is used following sorting, the handling of sperm post sorting, the sampling rate at which sperm are sorted, the apparatus used for sex sorting sperm, the sheath fluid used for the sorting process, the container used to collect sorted sperm, the effect of the staining procedure on sperm viability, and the use of frozen versus non-frozen sperm – that are inapplicable to the current claims, as claim 124 does not recite any sorting or freezing steps. Additionally, several additional factors – such as the methodology used for superovulating the bovine and the previous breeding history of the heifer – are well known in the art and have been addressed in protocols and procedures developed over many years of practice in the artificial insemination field. Review of the references cited in the various information disclosure statements provided by the Applicant should be sufficient to reveal that this is the case. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. MPEP § 2164.08. Finally, with respect to the side of insemination, the Applicant points out this factor nowhere is described in the specification using the language of criticality, *e.g.*, terms such as “essential”, “must”, *etc.*, have not been used to describe this technique. Without such language of criticality, the Applicant is unclear as to the Office’s basis for asserting that this is a critical parameter. To the contrary, the specification at page 24, lines 9-11, states that “samples thus far studied have shown no difference between ipsi- and contra-lateral inseminations when accomplished deep within the uterine horn”. For these reasons, the Applicant believes no enablement issues are raised by the factors listed in the Office Action.

CONCLUSION

The Applicant, having addressed each of the concerns raised in the Office Action, respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 124-141 is requested at the Examiner's earliest convenience.

Dated this 24 day of May, 2007.

Respectfully submitted,

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